II. Remarks/Arguments

Claims 1–18 were previously pending, of which claims 15–18 have been canceled, claim 14 has been amended, and no claims have been added. Claims 19–53 were previously withdrawn, of which claims 19–53 have been canceled. Reconsideration of presently pending claims 1–14 is respectfully requested in light of the above amendments and the following remarks.

The Examiner's indication of allowability for claim 14 is appreciated. The claim has been amended to overcome the rejection under 35 U.S.C. §112 and is believed to be in condition for allowance.

Rejections Under 35 U.S.C. § 112

Claims 2-3, 14, and 18 were rejected under 35 U.S.C. § 112, second paragraph. Examiner asserts that the claims were "indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention."

Claims 2–3 and 18 were rejected as unclear because Examiner states "[i]t is unclear in view of the prior art (including Ross et al), the scope of the term 'cam.'" Claim 18 has been canceled. The term "cam" should be understood in line with its use in the specification and its ordinary meaning. For example, Applicants direct Examiner's attention to Figure 2b and paragraph [0051] of the application which states that the "cam devices 80, 82 are moveable between an open position...and a closed position" and that the "cam devices...aid in securing." Thus, Applicants submit that the meaning of "cam device" is clear from the disclosure in the application. Therefore, Applicants respectfully request that the Examiner withdraw the \$ 112 rejections of claims 2–3.

Claim 14 was rejected as having insufficient antecedent basis for the limitation "the locking device." Per Examiner's request, Applicants have amended claim 14 to have proper antecedent basis by changing "locking devices" to "retaining devices." Therefore, Applicants respectfully request that the Examiner withdraw the § 112 rejections of claim 14.

Thus, in light of the above amendments and remarks, Applicants respectfully request that the Examiner withdraw the § 112 rejections of claims 2-3 and 14.

Rejections Under 35 U.S.C. § 102

- Allen (U.S. Patent No. 5,658,335) -

Claims 16–18 were rejected under 35 U.S.C. § 102(b) as being anticipated by Allen (US Patent No. 5,658,335 hereinafter referred to as "Allen"). Claims 16–18 have been canceled without prejudice to further consideration in a continuing application.

- Simonson (U.S. Patent No. 6,572,653) -

Claims 1, 4–13, and 15–17 were rejected under 35 U.S.C. § 102(b) as being anticipated by Simonson (US Patent No. 6,572,653 hereinafter referred to as "Simonson"). Claims 15–17 have been canceled. Applicants respectfully traverse the rejections of claims 1 and 4–13.

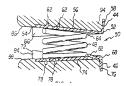
The PTO provides in MPEP § 2131 that

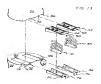
"[t]o anticipate a claim, the reference must teach every element of the

Therefore, to sustain the rejection of these claims, Simonson must teach all of the claimed elements. However, Simonson fails to disclose all of the claimed elements of independent claim 1, and therefore, dependent claims 4–13.

Independent Claim 1

Simonson fails to disclose all of the claimed elements of independent claim 1. Specifically, Simonson does not teach "a second surface in an opposed relation to the first surface, a first sidewall, a second sidewall, and a back wall extending from the second surface to define a socket adapted to receive a portion of the prosthetic insertion device." Figures 4 and 13 of Simonson are shown below:





As shown above, Simonson fails to teach "a back wall extending from the second surface." Figure 4 has only two sidewalls 66, "raised side edges 66 which taper along the length of the support" (column 4, lines 56–57), extending from a second surface. Figure 13 also shows that Simonson teaches only raised side edges 66, and not a back wall extending from the second surface.

Also, with respect to independent claim 1, Simonson fails to teach "at least one retention member moveable between a first position outside of the socket for allowing the portion of the prosthetic insertion device to slide within the socket and a second position at least partially within the socket to inhibit sliding of the portion of the prosthetic insertion device within the socket." Examiner asserts that the springs 48 constitute a prosthetic insertion device. Simonson teaches that "[t]he raised side edges 66, along with the retainer 64, function in locking the spring 48 into position between opposing supports (44 and 46)" (column 4, lines 60–63). Simonson teaches that the raised side edges 66 "prevent the lateral movement of the spring 48" (column 6, line 25) and the retainer 64 "precludes the spring from moving longitudinally" (column 6, line 26–27) back through the insertion opening. Simonson never teaches that there is a "retention member moveable between a first position...allowing the portion of the prosthetic insertion device to slide...and a second position...to inhibit sliding of the portion of the prosthetic insertion device." Further, no figures in Simonson teach any member or device that is moveable between a first and second position. Teaching only that raised side edges 66 "prevent the lateral movement of the spring 48" (column 6, line 25) and the retainer 64 "precludes the spring from moving longitudinally" (column 6,

line 26-27) does not teach a retention member that moves from a first to second position to allow and inhibit sliding.

Thus, Simonson fails to disclose all of the claimed elements of independent claim 1, and the rejection under 35 U.S.C. § 102 should be withdrawn.

Dependent Claims 4-13

Claims 4–13 are dependent claims that depend from and further limit independent claim 1. Since independent claim 1 overcomes the prior art references and is in condition for allowance, Applicants respectfully submit that dependent claims 4–13 are patentable over the cited art.

- Ross (U.S. Patent Publication No. 2003/0187506 A1) -

Claims 15–18 were rejected under 35 U.S.C. § 102(b) as being anticipated by Ross, et al. (US Patent Publication No. 2003/0187506 A1 hereinafter referred to as "Ross"). Claims 15–18 have been canceled without prejudice to consideration in a continuing application.

Rejections Under 35 U.S.C. § 103

Claims 1–13 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Ross, et al. (US Patent Publication No. 2003/0187506 A1 hereinafter referred to as "Ross") in view of Fraser, et al. (US Patent Publication No. 2004/0193271 A1 hereinafter referred to as "Fraser"). Applicants traverse the rejection of claims 1–13 on the grounds that the Ross and Fraser references are defective in establishing a prima facie case of obviousness with respect to claims 1–13.

As the PTO recognizes in MPEP § 2142:

... The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. If the examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of nonobviousness... It is submitted that, in the present case, the Examiner has not factually supported a prima facie case of obviousness for the following, mutually exclusive, reasons.

Independent Claim 1

1. Even When Combined, the References Do Not Teach the Claimed Subject Matter

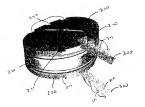
The Ross and Fraser references cannot be applied to reject claim 1 under 35 U.S.C. § 103(a).

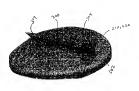
Neither Ross nor Fraser teach "a back wall extending from the second surface to define a socket adapted to receive a portion of the prosthetic insertion device."

As Examiner points out, Ross fails to teach a back wall extending from the second surface. Ross teaches that a "connecting element 30 can be formed on one or both of the attachment members 22, 24 and the mating surface 14_b, 16_b of each endplate member 14, 16" (paragraph [0041]). Applicants respectfully contend that only teaching one a "connecting element 30 can extend between the posterior side 26 and the anterior side 28...such that the endplate members 14, 16 are slidably matable to the attachment members 22, 24" (paragraph [0042]) does not teach "a back wall extending from the second surface to define a socket adapted to receive a portion of the prosthetic insertion device" as required in claim 1. Further, no figures in the Ross reference indicate or suggest that a back wall extends from the mating surfaces 14_b, 16_b to define a socket.

Even in view of Fraser, Fraser does not teach one skilled in the art to have "a first sidewall, a second sidewall, and a back wall extending from the second surface to define a socket adapted to receive a portion of the prosthetic insertion device." In fact, Fraser specifically teaches away from having any walls extending "from the second surface to define a socket adapted to receive a portion of the prosthetic insertion device." The Fraser reference specifically teaches that "[t]he surfaces of the endplates [210, 220] should contain relatively small, if any, projections therefrom" (paragraph [0045]). The Fraser reference only teaches that the endplate surfaces may "include recessed mating features 240 for accepting modular projections 300" (paragraph [0045]).

Figures 7B and 8A of Fraser are shown below:





As shown in Figures 7B and 8A above, though Fraser teaches, as the Examiner notes, "the dovetail extending from a first end to a second end" and a "dovetail extending from a first end to a distance to short of the second end," Fraser teaches that such dovetail extension is on the first surfaces, the surfaces with the securing feature 304 that "engages the vertebral endplates and secures the artificial disc" (paragraph [0046]), of the endplates 210, 220. Fraser never indicates or suggests that a back wall, or a first or second wall, should extend from the second surface, the surface in contact with the flexible core 230, of the endplates 210, 220. Fraser only teaches having the dovetail extensions from the first surface. the surface that engages the vertebrae. Applicants respectfully contend that Fraser's teaching that "ft]he surfaces of the endplates [210, 220] should contain relatively small, if any, projections therefrom" (paragraph [0045]) does not teach "a first sidewall, a second sidewall, and a back wall extending from the second surface to define a socket adapted to receive a portion of the prosthetic insertion device." All figures in the Fraser reference indicate or suggest only having "recessed mating features 240" (paragraph [0045]). Further, no figures in the Fraser reference indicate or suggest that a back wall extends from the "recessed mating features 240" or the second surfaces of the endplates to define a socket. Fraser fails to teach altogether a way for securing the endplates 210, 220 to 230. Thus, because Fraser specifically suggests that the endplate surfaces should be free of protrusions, and never suggests having the dovetail

extensions on the second surface, one skilled in the art would not modify Ross in view of Fraser to have "a back wall extending from the second surface."

Neither Ross, Fraser, nor Ross in view of Fraser teach "a back wall extending from the second surface to define a socket adapted to receive a portion of the prosthetic insertion device." Thus, for this mutually exclusive reason, the Examiner's burden of factually supporting a *prima facie* case of obviousness has clearly not been met, and the rejection under 35 U.S.C. § 103(a) should be withdrawn.

2. Prior Art That Teaches Away From the Claimed Invention Cannot be Used to Establish Obviousness

Examiner contends that Ross in view of Fraser teaches "a back wall extending from the second surface to define a socket adapted to receive a portion of the prosthetic insertion device." However, the Fraser reference teaches away from having any wall, much less a back wall, extending from the second surface. In the present case, the Fraser reference by specifically teaching in claims 5 and 10:

"a superior surface and an inferior surface, the surfaces having no significant protrusions extending therefrom"

clearly teaches away from independent claim 1, which requires:

"a second surface in an opposed relation to the first surface, a first sidewall, a second sidewall, and a back wall extending from the second surface to define a socket adapted to receive a portion of the prosthetic insertion device."

As discussed above, Fraser teaches away from having a back wall, or a first or second wall, extending from the second surface of the endplates 210, 220. To the contrary, Fraser emphasizes that "the surfaces of the endplates should contain relatively small, if any projections therefrom." Such emphasis teaches away from having a back wall, or a first and second sidewall, or any wall protruding from the surface. Further, the only feature Fraser teaches on the surfaces are "recessed mating features 240" on the first surfaces, the vertebral-engaging surfaces, of the endplates. Applicants respectfully contend that the Fraser reference specifically teaching "a superior surface and an inferior surface, the surfaces having no significant protrusions extending therefrom." and features only on the first surfaces of the endplates.

teaches away from claim 1 which teaches "a second surface in an opposed relation to the first surface, a first sidewall, a second sidewall, and a back wall extending from the second surface to define a socket adapted to receive a portion of the prosthetic insertion device." Therefore, since Fraser teaches away from having a back wall extending from the second surface, one skilled in the art would not use Ross in view of Fraser to have such back wall

Thus, for this reason alone, the Examiner's burden of factually supporting a prima facie case of obviousness has clearly not been met, and the rejection to claim 1 under 35 U.S.C. § 103(a) should be withdrawn

3. The Combination of References is Improper

Assuming, arguendo, that none of the above arguments for non-obviousness apply (which is clearly <u>not</u> the case based on the above), there is still another, mutually exclusive, and compelling reason why the Ross and Fraser references cannot be applied to reject claim 1 under 35 U.S.C. § 103(a).

§ 2142 of the MPEP also provides:

...the examiner must step backward in time and into the shoes worn by the hypothetical 'person of ordinary skill in the art' when the invention was unknown and just before it was made.... The examiner must put aside knowledge of the applicant's disclosure, refrain from using hindsight, and consider the subject matter claimed is a whole?

One of ordinary skill in the art would not have been led to modify Ross's and Fraser's teaching to extend a back wall from the second surface, because there is no teaching or suggestion in Ross or Fraser to do so. To the contrary, as discussed above, Fraser specifically discloses "the surfaces of the endplates should contain relatively small, if any, projections therefrom" (paragraph [0045]). And, the Fraser reference only suggests having "at least one modular protrusion 300...inserted into the superior and inferior endplates 210, 220...to secure the disc 200 to vertebral endplates" (paragraph [0043]) on the endplate's first surfaces. Fraser never suggests having any protrusions to secure the flexible core 230 to the second surfaces of the endplates 210, 220.

Further, the Ross reference gives no incentive or motivation to have a back wall extending from the second surface, noting that the connecting element 30's "complementary members can be dimensioned to provide a frictional or interference fit to fixedly or securely mate the endplate members 14, 16 to the attachment members 22, 24" (paragraph [0041]). Ross also suggests that "a positive locking mechanism which is effective to prevent virtually any movement of the endplate members 14, 16" (paragraph [0043]) can be utilized for securing the device. Such statements do not give one skilled in the art incentive or motivation to form "a back wall such to provide a stop between the end members and the prosthetic insertion device and better securing them together" as Examiner contends.

Even with Ross in view of Fraser, one skilled in the art would note that Fraser stresses having no protrusions on the surfaces of the endplates, and further indicates that the only features on the endplates should be on the first surfaces. Therefore, in Ross, Fraser, or Ross in view of Fraser, there is no teaching or incentive to have "a second surface in an opposed relation to the first surface, a first sidewall, a second sidewall, and a back wall extending from the second surface to define a socket adapted to receive a portion of the prosthetic insertion device." Thus, it is clear that neither reference provides any incentive or motivation supporting the desirability of the combination. Therefore, there is simply no basis in the art for combining the references to support a 35 U.S.C. § 103(a) rejection.

In this context, the MPEP further provides at § 2143.01:

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.

In the above context, the courts have repeatedly held that obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination.

In the present case it is clear that the Examiner's combination arises solely from hindsight based on the invention without any showing, suggestion, incentive or motivation in either reference for the

Patent / Docket No. PC912.00 / 31132.153

combination as applied to claim 1. Therefore, for this mutually exclusive reason, the Examiner's burden of factually supporting a prima facie case of obviousness has clearly not been met, and the rejection under

35 U.S.C. § 103(a) should be withdrawn.

Dependent Claims 2-13

Claims 2-13 are dependent claims that depend from and further limit independent claim 1. Since independent claim 1 overcomes the prior art references and is in condition for allowance, Applicants

respectfully submit that dependent claims 2-13 are patentable over the cited art.

Conclusion

It is clear from all of the foregoing that independent claims 1 and 14 are in condition for allowance. Dependent claims 2-13 depend from and further limit independent claim 1 and therefore are allowable as well

Notice of allowance of claims 1-14 is requested. An early action on the merits is respectfully requested.

Respectfully submitted,

Registration No. 40,706

S. Andrew Lowes

HAYNES AND BOONE, LLP 901 Main Street, Suite 3100 Dallas, Texas 75202-3789 Telephone: 972-681-7557 IP Facsimile No. 214-200-0853

R142639

Certificate of Service

I hereby certify that this correspondence is being deposited with the U.S. Patent and Trademark Office via EFS-Web

Underwood

on September 5, 2006.

Karen I. Underwood